IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.: 10/699,025 Confirmation No.: 2143
Appellant: Stephen Bennett Elliott
Filed: 11/03/2003
Art Unit: 3766
Examiner: Mark Bockelman
Title: **METHOD AND SYSTEM FOR CONSCIOUSLY SYNCHRONIZING THE BREATHING CYCLE WITH THE NATURAL HEART RATE CYCLE**

Docket No.: 1119-003
Customer No.: 27820

Mail Stop Appeal Brief – Patents
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

An **APPEAL BRIEF** is filed herewith. Appellant encloses a payment in the amount of $270.00 as required by 37 C.F.R. § 1.17(b) and a payment in the amount of $245.00 to cover the fee associated with a Two-month Extension of Time for a small entity and requests that this be considered a petition therefor. If any additional fees are required in association with this appeal brief, the Director is hereby authorized to charge them to Deposit Account 50-1732, and consider this a petition therefor.

APPEAL BRIEF

(1) REAL PARTY IN INTEREST

The real party in interest is the assignee of record, i.e., Coherence LLC of 702 Buffalo Springs Drive, Allen, Texas 75013.

(2) RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences to the best of Appellant's knowledge.

(3) STATUS OF CLAIMS

Claims 1, 5, 7, 9, 11-15, 17-20, 22, and 24 were rejected with the rejection made final on April 3, 2009.

Claims 2-4, 6, 8, 10, 16, 21, 23, and 25 have been previously cancelled. Claims 26-45 were withdrawn.

Claims 1, 5, 7, 9, 11-15, 17-20, 22, and 24 are pending and are the subject of this appeal.

(4) STATUS OF AMENDMENTS

All amendments have been entered to the best of Appellant's knowledge. No amendments have been made after the final rejection mailed April 3, 2009.

(5) SUMMARY OF CLAIMED SUBJECT MATTER

In the following summary, Appellant has noted where in the Specification (paragraph cites are to U.S. Patent Application Publication No. 2005/0096555 A1) certain subject matter exists. Appellant wishes to point out that these citations are for demonstrative purposes only and that the Specification may include additional discussion of the various elements, citations to which are not pointed out below. Thus, the noted citations are in no way intended to limit the scope of the pending claims.

Independent claim 1 recites a method for consciously synchronizing a breathing cycle of a human subject with a natural heart rate of the human subject, the method comprising:

monitoring the natural heart rate of the human subject (Specification, paragraphs 0021, 0022, and 0025-0027; see also Figures 1-3);

detecting a transition in the natural heart rate from a maximum heart rate (Specification, paragraphs 0020, 0022, 0023 and 0025-0027; see also Figures 1, 4, and 6);

providing a first biofeedback signal to the human subject to indicate that the natural heart rate has reached the maximum heart rate (Specification, paragraphs 0007, 0010, 0019-0022, and 0025-0037; see also Figures 1-6);

detecting a transition in the natural heart rate from a minimum heart rate (Specification, paragraphs 0020, 0022, 0023, and 0025-0027; see also Figures 1, 4, and 6);

providing a second biofeedback signal to the human subject to indicate that the natural heart rate has reached the minimum heart rate (Specification, paragraphs 0007, 0010, 0019-0022, and 0025-0037; see also Figures 1-6); and

instructing the human subject, via the second biofeedback signal, an exact moment to begin inhalation and instructing the human subject, via the first biofeedback signal, an exact

moment to begin exhalation, such that the human subject aligns their breathing with the natural heart rate to attempt to achieve consistency in the natural heart rate, wherein the instruction provided to the human subject to begin exhalation is provided by a first feedback type and the instruction provided to the human subject to begin inhalation is provided by a second feedback type (Specification, paragraphs 0007, 0010, 0019-0022, and 0025-0037; see also Figures 1-6).

(6) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Whether claims 1, 3, 5, 7, 9, 11-15, 17-20, 22, and 24 were properly rejected under 35 U.S.C. § 112 as failing to comply with the written description requirement. Claim 3 was previously cancelled in the amendment filed on September 14, 2007, thereby rendering the rejection of this claim moot.

B. Whether claims 1, 3, 5, 7, 9, 11-15, 17-20, 22, and 24 were properly rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,997,482 to Vaschillo et al. (hereinafter "Vaschillo"). Claim 3 was previously cancelled in the amendment filed on September 14, 2007, thereby rendering the rejection of this claim moot.

C. Whether claims 1, 3, 5, 7, 9, 11-15, 17-20, and 22 were properly rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,836,681 B2 to Stabler et al. (hereinafter "Stabler"). Claim 3 was previously cancelled in the amendment filed on September 14, 2007, thereby rendering the rejection of this claim moot.

(7) ARGUMENT

A. Introduction

In response to the rejection of the claims under 35 U.S.C. § 112 as failing to comply with the written description requirement, Appellant refers to paragraphs 0007, 0010, 0019, 0021, 0022, and 0025-0037 of the Specification as published in U.S. Patent Application Publication No. 2005/0096555 A1. Appellant asserts that these paragraphs, despite not using the exact words, when read in conjunction with the entire Specification, disclose and support the claimed step of "instructing the human subject, via the second biofeedback signal, an exact moment to begin inhalation and instructing the human subject, via the first biofeedback signal, an exact moment to begin exhalation, such that the human subject aligns their breathing with the natural heart rate to attempt to achieve consistency in the natural heart rate, wherein the instruction

provided to the human subject to begin exhalation is provided by a first feedback type and the instruction provided to the human subject to begin inhalation is provided by a second feedback type." For example, paragraph 0007 states that the human subject is presented "**with a biofeedback signal that indicates exactly when to inhale and exactly when to exhale such that the breathing cycle achieves exacting alignment with the natural heart rate variability cycle**." Likewise, paragraph 0010 states that "a specific **instructive** method employing other biofeedback devices and methods is specified. Via the application of this **instructive** method, the human subject is **led to** achieve a detectable level of synchrony of their heart rate variability signal." The above paragraphs, as well as other disclosures in the Specification make it clear to one of ordinary skill in the art that Appellant had possession of the claimed step of "instructing the human subject, via the second biofeedback signal, an exact moment to begin inhalation and instructing the human subject, via the first biofeedback signal, an exact moment to begin exhalation," as recited in claim 1.

With respect to the anticipation and obviousness rejection of the claims, the Patent Office has not shown where all the elements of the pending claims are in the prior art with sufficient particularity to sustain an anticipation rejection or an obviousness rejection. In particular, the Patent Office has not shown where either Vaschillo or Stabler discloses or suggests each and every limitation of independent claim 1. Vaschillo does not teach or suggest that the human subject "aligns their breathing with the **natural heart rate** to attempt to achieve consistency in the natural heart rate," as recited in claim 1. The claimed invention instructs the human subject on the actual breathing cycle such that the human subject breathes to align his breathing cycle to his natural heart rate cycle to attempt to achieve coherence. The claimed invention provides an instruction signal based on actual biofeedback from the human subject's heart rate cycle. Vaschillo does not teach or suggest using such a biofeedback signal to instruct a human subject to align his breathing cycle to his natural heart rate cycle to attempt to achieve coherence.

Moreover, Vaschillo does not teach or suggest "wherein the instruction provided to the human subject to begin exhalation is provided by a first feedback type and the instruction provided to the human subject to begin inhalation is provided by a second feedback type," as recited in claim 1, since Vaschillo does not disclose two different feedback types to provide the instructions to the human subject to begin inhalation and exhalation.

Stabler does not instruct a human subject to have him breathe at a target rate based on the user's heart rate cycle; thus, Stabler does not teach or suggest that the human subject "aligns their breathing with the **natural heart rate** to attempt to achieve consistency in the natural heart rate," as recited in claim 1. Like Vaschillo, Stabler leads the heart rhythm to synchronize with the breathing cycle by having the user breathe at a rhythm at which the heart rhythm synchronizes with the breathing cycle. However, this is fundamentally different than the claimed invention, which synchronizes the breathing cycle with the natural heart rate of the human subject by providing indications to inhale and exhale in synchrony with biofeedback signals derived from the human subject's natural heart rate. The key recognition of inhalation and exhalation in the breathing cycle to achieve coherence, as well as instructing the human subject specifically at the transition times as to when to inhale and exhale based on the human subject's natural heart rate, as set forth in the claimed invention, is not present in Stabler. In addition, Stabler does not teach or suggest "wherein the instruction provided to the human subject to begin exhalation is provided by a first feedback type and the instruction provided to the human subject to begin inhalation is provided by a second feedback type." Stabler does not disclose two different feedback types to provide the instructions to the human subject to begin inhalation and exhalation.

As such, Appellant requests that the Board reverse the Examiner and instruct the Examiner to allow the claims for these reasons along with the reasons noted below.

B. Summary Of References

1. U.S. Patent No. 5,997,482 To Vaschillo

Vaschillo is directed to a therapeutic method that includes determining heartbeat and respiratory rates converted in respective electric signals of a subject, displaying the heart rate, spectrally analyzing the respiratory and heartbeat signals, thereby defining a phase shift therebetween, causing the subject to modify the respiratory rate in a sense tending to minimize the phase shift and selecting a frequency of the displayed reference signal which correlates with the modified respiratory signal, and establishing an optimum reference signal displayed as a resonance frequency unique for the subject upon approaching the zero phase shift between the heart signal and the modified respiratory signal (Vaschillo, Abstract). Vaschillo instructs the user to breathe in accordance with a predetermined reference signal (RS) (Vaschillo, col. 6, lines.

52-55; see also Figure 2). The reference signal (RS) is not a biofeedback of the user's heartbeat rate, but is instead a predetermined signal at one possible breathing cycle frequency (Vaschillo, col. 6, lines 52-55). The user is instructed to breathe according to the reference signal (RS) on a display (8). The user is informed whether his breathing is in accordance with the reference signal (RS) (H/R signal in Figure 2). Vaschillo then records the user's heartbeat cycle that results from the user breathing at the reference signal (RS) frequency.

Vaschillo repeats these steps over a series of varied reference signal (RS) frequencies in a sweeping fashion. This data is then analyzed to determine at which reference signal (RS) frequency the user's breathing aligns (i.e., resonates) with his heartbeat cycle. Phase shift differences between the reference signal (RS) frequency and the user's heart rate are analyzed in the frequency domain to determine resonance, or lack therof. Zero phase shift represents resonance. Figures 4A and 4B of Vaschillo illustrate this data recordation and analysis. Thus, Vaschillo instructs the user to breathe based on a variety of reference signals (RS) and not on any biofeedback signal. Vaschillo is just a monitoring system that does nothing to instruct the user on how to align his breathing with his natural heart rate. Vaschillo's goal is to simply monitor and determine the current state of the user's heart rate cycle (i.e., the resonant frequency). No instructions are provided to the user to breathe according to his own natural heart rate or according to any other biofeedback.

2. U.S. Patent No. 6,836,681 To Stabler

Stabler is directed to a method of enabling a person to reduce tension as a way of improving the possibility that the person will reach a desired level of performance during a tension-causing event includes the steps of selecting a monitor capable of measuring the heart rate of a person and including a display constructed to show heart-rate variability (HRV), and connecting a person to the monitor (Stabler, Abstract). Stabler has the user breathe with a reference rhythm in such a way as to achieve "the zone" (Stabler, Figure 1). Stabler defines the zone as a frequency range wherein the spectral power of the heart rate should be maximized. It can be assumed that Stabler's "zone" is indicative that the heart rhythm is nearing alignment with the breathing cycle. Stabler acknowledges that when performed correctly, the user's heart rate can be seen to "follow the breathing cycle" (Stabler, col. 3, paragraph 7).

Stabler does not instruct a human subject to have him breathe at a target rate based on the user's heart rate cycle (Stabler, col. 2, lines 35-38). Instead, Stabler simply displays a graph of heart rate variability and amplitude of breathing results to the user. The graph only indicates to the user that he is in "the zone," which Stabler makes clear is relative to the amplitude of the HRV cycle. Stabler does not teach or suggest that these results provide instructions to the user to breathe such that the user aligns his breathing cycle with his heart rate cycle. Nor does the user in Stabler breathe according to the results provided on the display. The user is simply given the results to indicate if the user is in the "zone" without any real understanding of the relationship of inhalations and exhalations to transitions in the natural heart rate cycle (Stabler, col. 4, lines 1-17). Stabler simply requires the user to continue breathing in a controlled fashion until the user gets it right and reaches the "zone."

When the user is "in the zone," the heart rhythm will follow the breathing cycle. In Stabler, when the user is performing correctly, it should be seen that the heart rate is following the respiration (Stabler, col. 3, lines 53-64). Stabler's "zone" is also a broad indication of synchrony of the heart rhythm with the breathing cycle. Like Vaschillo, Stabler leads the heart rhythm to synchronize with the breathing cycle by having the user breathe at a rhythm at which the heart rhythm synchronizes with the breathing cycle.

C. Legal Standards

1. For Written Description

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. M.P.E.P. § 2163; *see also Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 U.S.P.Q.2d (BNA) 1429, 1438 (Fed. Cir. 2003). 35 U.S.C. § 112 does not require that the claimed invention subject matter be described literally, i.e., using the same terms, in order for the disclosure to satisfy the description requirement. M.P.E.P. § 2106. All that is required is that the claim limitations be supported in the specification through express, implicit, or inherent disclosure. M.P.E.P. § 2163.

2. For Establishing Anticipation

Section 102 of the Patent Act provides the statutory basis for an anticipation rejection and

states *inter alia*:

> A person shall be entitled to a patent unless
> ***
> (e) the invention was described in - (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language. . . .

The Federal Circuit's test for anticipation has been set forth numerous times. "It is axiomatic that for prior art to anticipate under 102 it has to meet every element of the claimed invention." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379 (Fed. Cir. 1986). This standard has been reinforced. "To anticipate a claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter." *PPG Indus. Inc. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1577 (Fed. Cir. 1996) (citations omitted). Further, "a finding of anticipation requires that the publication describe all of the elements of the claims, arranged as in the patented device." *C.R. Bard Inc. v. M3 Sys. Inc.*, 157 F.3d 1340, 1349 (Fed. Cir. 1998) (emphasis added and citations omitted).

3. For Establishing Obviousness

Section 103(a) of the Patent Act provides the statutory basis for an obviousness rejection and reads as follows:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Courts have interpreted 35 U.S.C. § 103(a) as a question of law based on underlying facts. As the Federal Circuit stated:

> Obviousness is ultimately a determination of law based on underlying determinations of fact. These underlying factual determinations include: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the

> differences between the claimed invention and the prior art; and (4) the extent of any proffered objective indicia of nonobviousness.

Monarch Knitting Mach. Corp. v. Sulzer Morat GmBH, 45 U.S.P.Q.2d (BNA) 1977, 1981 (Fed. Cir. 1998) (internal citations omitted).

Once the scope of the prior art is ascertained, the content of the prior art must be properly combined. "Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demand known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit. See *In re Kahn*, 441 F. 3d 977, 988 (Fed. Cir. 2006). "[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR Int'l v. Teleflex, Inc.*, 550 U.S. 398, 418, 82 U.S.P.Q.2d (BNA) 1385, 1396 (2007).

While the Patent Office is entitled to give claim terms their broadest reasonable interpretation, this interpretation is limited by a number of factors. First, the interpretation must be consistent with the specification. *In re Hyatt*, 211 F.3d 1367, 1372 (Fed. Cir. 2000); M.P.E.P. § 2111. Second, the broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach. *In re Cortright*, 165 F.3d 1353, 1359, (Fed. Cir. 1999); M.P.E.P. § 2111. Finally, the interpretation must be reasonable. *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1369 (Fed. Cir. 2004); M.P.E.P. § 2111.01. This means that the words of the claim must be given their plain meaning unless Appellant has provided a clear definition in the specification. *In re Zletz*, 893 F.2d 319, 321 (Fed. Cir. 1989).

When rejecting a claim under § 103, the Patent Office must either show that the prior art references teach or suggest all limitations of the claim or explain why the difference(s) between the prior art and the claimed invention would have been obvious to one of ordinary skill in the art. Examination Guidelines for Determining Obviousness Under 35 U.S.C. § 103 in View of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.*, published in the Federal Register, Vol. 72, No. 195, pages 57526-57535. The gap between the prior art and the claimed invention may not be "so great as to render the [claim] nonobvious to one reasonably skilled in the art." *Dann v. Johnston*, 425 U.S. 219, 230, 189 U.S.P.Q. (BNA) 257, 261 (1976).

To establish *prima facie* obviousness, the Patent Office must show where each and every element of the claim is taught or suggested in the combination of references. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. (BNA) 580 (CCPA 1974). If a claim element is missing after the combination is made, then the combination does not render obvious the claimed invention, and the claims are allowable. As stated by the Federal Circuit, "[if] the PTO fails to meet this burden, then the applicant is entitled to the patent." *In re Glaug,* 283 F.3d 1335, 1338 (Fed. Cir. 2002).

D. Claims 1, 5, 7, 9, 11-15, 17-20, 22, And 24 Comply With The Written Description Requirement Under 35 U.S.C. § 112

Claims 1, 5, 7, 9, 11-15, 17-20, 22, and 24 stand rejected under 35 U.S.C. § 112 as failing to comply with the written description requirement.

In particular, the Patent Office alleges that the claim language regarding instructing the human subject via the first and second feedback signal is not described in the Specification because the Specification "only has the feedback signal providing and (sic) indication to the patient and instruction further provided for the patient by a person instructing the patient." (Final Office Action mailed April 3, 2009, p. 2). Appellant respectfully disagrees.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. M.P.E.P. § 2163; *see also Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 U.S.P.Q.2d (BNA) 1429, 1438 (Fed. Cir. 2003). Notably, 35 U.S.C. § 112 does not require that the claimed invention subject matter be described literally, i.e., using the same terms, in order for the disclosure to satisfy the description requirement. M.P.E.P. § 2106. All that is required is that the claim limitations be supported in the specification through express, implicit, or inherent disclosure. M.P.E.P. § 2163. Appellant refers to paragraphs 0007, 0010, 0019, 0021, 0022, and 0025-0037 of the Specification as published in U.S. Patent Application Publication No. 2005/0096555 A1.

Appellant asserts that these paragraphs, despite not using the exact words, when read in conjunction with the entire Specification, disclose and support the claimed step of "instructing the human subject, via the second biofeedback signal, an exact moment to begin inhalation and instructing the human subject, via the first biofeedback signal, an exact moment to begin

exhalation, such that the human subject aligns their breathing with the natural heart rate to attempt to achieve consistency in the natural heart rate, wherein the instruction provided to the human subject to begin exhalation is provided by a first feedback type and the instruction provided to the human subject to begin inhalation is provided by a second feedback type."

In particular, paragraph 0007 states in part:

> The most direct and effective manner of achieving this alignment is for the human subject to consciously align them via biofeedback, i.e., present the human subject **with a biofeedback signal that indicates exactly when to inhale and exactly when to exhale such that the breathing cycle achieves exacting alignment with the natural heart rate variability cycle**.

Likewise, paragraph 0010 states:

> Because the heart rate variability signal of the untrained subject is typically highly erratic and synchrony of said signal may be difficult to detect, a specific **instructive** method employing other biofeedback devices and methods is specified. Via the application of this **instructive** method, the human subject is **led to** achieve a detectable level of synchrony of their heart rate variability signal.

Paragraph 0019 reads in part:

> This is accomplished by providing a biofeedback signal in the form of an audible, visual, or sensory stimulus, **to indicate when the subject should begin inhalation and a second signal to indicate when the subject should begin exhalation**. These signals are unique so the subject is able to clearly distinguish the beginning of inhalation from the beginning of exhalation.

Paragraph 0025 discloses that "**via biofeedback, the human subject is trained** to identify the subjective state and associated sensation that relates to maximal alignment."

In light of the above description in the Specification, and reading the Specification as a whole, Appellant respectfully submits that the instructing via feedback signals step of the claims is either expressly or implicitly supported by the written description contained in the Specification. Appellant therefore respectfully submits that one of ordinary skill in the art would recognize that the application had possession of the invention as claimed at the time that the application was filed. The rejection under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement should be withdrawn.

E. Claims 1, 5, 7, 9, 11-15, 17-20, 22, And 24 Are Patentable Over Vaschillo

Claims 1, 5, 7, 9, 11-15, 17-20, 22, and 24 stand rejected under 35 U.S.C. § 102(b) over

Vaschillo. Appellant respectfully traverses the rejection. For the Patent Office to prove anticipation, each and every element of the claims must be present in the reference. Furthermore, the elements of the reference must be arranged as claimed. M.P.E.P. § 2131. Vaschillo does not teach each and every limitation of independent claim 1.

By way of background, Appellant refers to paragraph 0007 of the Specification:

> As previously described, a relationship exists between the heartbeat rate specified in terms of heart rate variability, and the breathing cycle. While the heart has its own tendency toward a natural variable rhythm, there is a strong correlation with breathing according to this specific relationship: as inhalation occurs, there is a tendency for the heartbeat rate to increase, as exhalation occurs, there is a tendency for the heartbeat rate to decrease. It is important to note that the relationship between the natural heart rate variability cycle and the breathing cycle is indirect. This is to say that while the heart rate variability cycle/breathing cycle relationship exists, in untrained subjects, their alignment appears highly random. Consequently, these same subjects exhibit a highly incoherent heart rate variability pattern. As previously stated, maximal coherence of the heart rate variability is achieved when the cycle of breathing is synchronized with the natural heart variability cycle in time and amplitude.

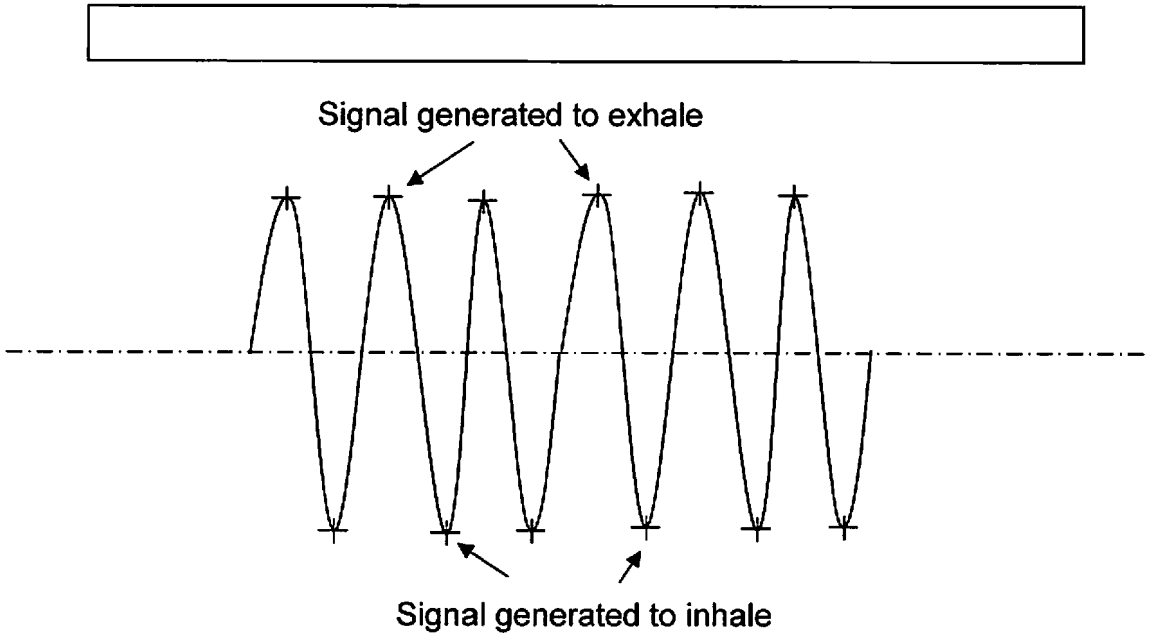
In addition, in the present application, the heart rate variability cycle (the periodicity of increasing and decreasing heart rate) and the breathing cycle (the periodicity of inhalation and exhalation) are considered to be two independent cycles (Specification, paragraph 0008). Before addressing the rejections, Appellant believes it would be beneficial to explain the claimed invention and its goals, as well as examples of such.

The goal of Appellant's invention is to facilitate maximization of coherence of a patient's heartbeat rate variability (HRV). HRV is the variation in periodicity and amplitude of the natural heartbeat rate over time. An irregular or inconsistent HRV is typically associated with physiological and emotional stress. On the other hand, a more consistent HRV is typically associated with physiological harmony. A highly coherent HRV results in a level of consistency in periodicity and amplitude of the natural heartbeat rate cycle over time. Hence, the use of the term "coherence." "Coherence" is achieving a level of consistency in a patient's HRV to reduce or improve physiological harmony and emotional stress. The goal of the claimed invention is to instruct the patient on how to breathe to achieve coherence.

As discussed in paragraph 0007 of the Specification, the inventor recognized that although a heartbeat rate cycle has its own natural variable rhythm, there is a strong correlation between a heartbeat rate cycle and the breathing cycle. This is to say that while the HRV cycle

and breathing cycle relationship exists, in untrained subjects, their alignment appears random. As illustrated in Figure 2 of the present application, when the natural heartbeat rate cycle and breathing cycle are misaligned (as shown on the left side of the top graph), the resulting HRV below is highly incoherent. However, when the natural heartbeat rate cycle and breathing cycle are aligned, the natural heart beat rate cycle becomes more consistent. This results in a highly coherent HRV, as shown in the bottom graph of Figure 2. Thus, a patient is instructed on how to align his breathing cycle with his natural heartbeat rate cycle based on the feedback of the heartbeat cycle transitions to achieve greater consistency in a natural heartbeat rate cycle and in turn a more coherent HRV.

These concepts are consistent with the claimed invention. In this regard, claim 1 of the application monitors a patient's heartbeat in the time domain. The transitions of the heartbeat rate are presented to the user, which may be in the form of individual audible, visual, or tactile biofeedback signals. The biofeedback signals are presented to the patient in the time domain as individual indications. The biofeedback signals indicate transitions in the natural heart rate from both a maximum and minimum heart rate. The moments of biofeedback indication are illustrated by the exemplary HRV cycle below.



Next, the patient is instructed when to inhale and when to exhale to synchronize his breathing with his heartbeat cycle as indicated by the indicators to inhale and exhale. In this manner as discussed above, as the patient's heartbeat rate cycle and breathing cycle become

aligned, the heartbeat rate cycle becomes more consistent. Thus, HRV becomes more coherent. The biofeedback signals presented to the user are in the time domain, because these biofeedback signals are used to instruct the patient on how to breathe in the time domain.

Embodiments disclosed in the present application achieve synchrony of the breathing cycle with the heart rhythm by monitoring the heart rate and consciously synchronizing the breathing cycle with the heart rhythm. The goal of the claimed invention is to achieve synchrony of the breathing cycle with the heart rhythm based on the natural heart rate of the human subject, not to synchronize the heart rhythm with the breathing cycle, as is done in Vaschillo and Stabler. Vaschillo and Stabler both attempt to assess and determine a given user's ideal breathing frequency, then have the user breathe at that frequency in order to realize health benefit. The intent of the claimed invention is to have the human subject breathe directly in synchrony with his natural heart rhythm. Therefore, in the case of the claimed invention, the subject's heart rate itself serves as a breathing "reference rhythm." Scientifically, this is a fundamentally different method employing a different psychophysiological mechanism than the method employed by Vaschillo and Stabler. It can be seen that both the goals and the methods of Vaschillo and Stabler are different from the goal and method of the claimed invention, so it is not surprising that neither Vaschillo nor Stabler teaches or suggests each and every element of the claimed invention.

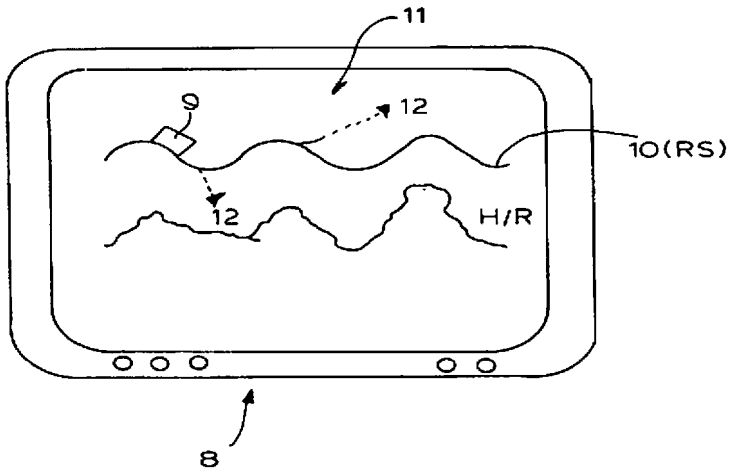
Claim 1 provides that the human subject is instructed on the moment to breathe such that the human subject aligns their breathing with the natural heart rate to attempt to achieve consistency in the natural heart rate. Greater consistency results in a more coherent HRV cycle. Greater consistency in a human subject's natural heart rate can be achieved by a human subject aligning his breathing cycle with his natural heart rate cycle. The claimed invention provides this breathing instruction to the human subject such that the human subject aligns his breathing cycle to his natural heart rate cycle. The human subject breathes in response to the instruction to align his breathing cycle with his natural heart rate cycle. This is in response to the inventor's recognition of the relationship that exists between respiration and heart rate.

In contrast to the claimed invention, which achieves synchrony of the breathing cycle with the heart rhythm by monitoring the heart rate and consciously synchronizing the breathing cycle with the heart rhythm, Vaschillo achieves synchrony of the heart rhythm with the breathing cycle by having the user breathe at a variable reference rhythm, then adjusting that rhythm until

the heart rhythm aligns with the reference rhythm. Vaschillo therefore has the user breathe at a reference rhythm, rather than at a first and second biofeedback signal that indicates that the natural heart rate of the human subject has reached the maximum and minimum heart rate. Vaschillo therefore does not teach or suggest that the human subject "aligns their breathing with the **natural heart rate** to attempt to achieve consistency in the natural heart rate," as recited in claim 1.

Vaschillo does not instruct a human subject to breathe based on his natural heart rate cycle, as provided in the claimed invention. Instead, as illustrated in Figure 2 below, Vaschillo instructs the user to breathe in accordance with a predetermined reference signal (RS) (Vaschillo, col. 6, lines 52-55). The reference signal (RS) is not a biofeedback of the user's heartbeat rate, but is instead a predetermined signal at one possible breathing cycle frequency (Vaschillo, col. 6, lines 52-55). The user is instructed to breathe according to the reference signal (RS) on a display (8). The user is informed whether his breathing is in accordance with the reference signal (RS) (H/R signal in Figure 2). Vaschillo then records the user's heartbeat cycle that results from the user breathing at the reference signal (RS) frequency.

FIG. 2



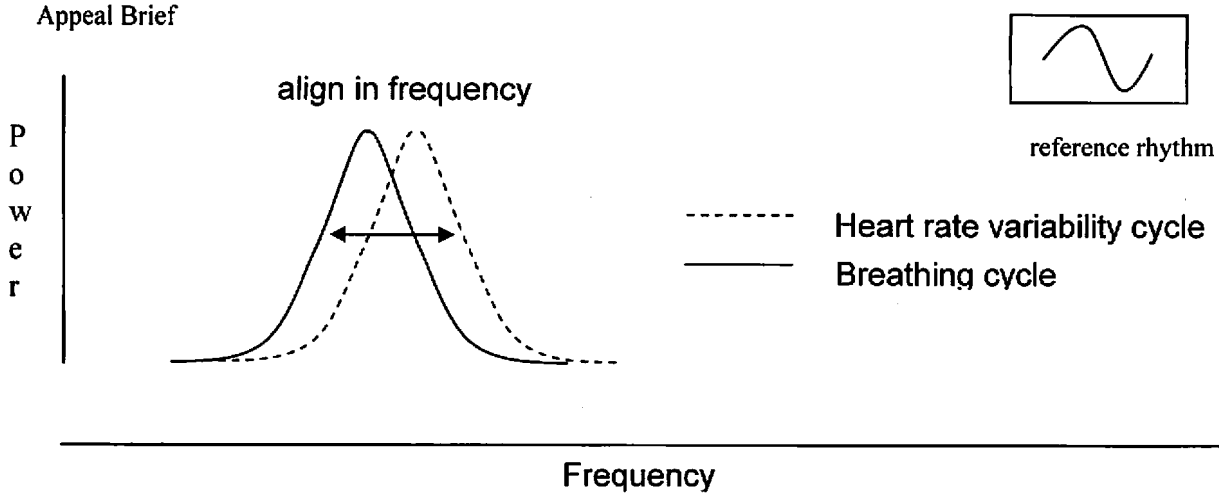
Vaschillo repeats these steps over a series of varied reference signal (RS) frequencies in a sweeping fashion. This data is then analyzed to determine at which reference signal (RS) frequency the user's breathing aligns (i.e., resonates) with his heartbeat cycle. Phase shift differences between the reference signal (RS) frequency and the user's heart rate are analyzed in

the frequency domain to determine resonance, or lack therof. Zero phase shift represents resonance. Figures 4A and 4B of Vaschillo illustrate this data recordation and analysis.

Thus, Vaschillo instructs the user to breathe based on a variety of reference signals (RS) and not on any biofeedback signal. Vaschillo is just a monitoring system that does nothing to instruct the user on how to align his breathing with his natural heart rate. Vaschillo's goal is to simply monitor and determine the current state of the user's heart rate cycle (i.e., the resonance frequency). No instructions are provided to the user to breathe according to his own natural heart rate or any other biofeedback.

On the contrary, the claimed invention is not a tool to quantify resonance based on theoretical breathing reference signals like in Vaschillo. The claimed invention instructs the human subject on the actual breathing cycle such that the human subject breathes to align his breathing cycle to his natural heart rate cycle to attempt to achieve coherence. The claimed invention provides an instruction signal based on actual biofeedback from the human subject's heartbeat cycle. Vaschillo does not. Vaschillo is designed to analyze the current state of the user's heartbeat. The claimed invention is designed to instruct and have the human subject breathe to achieve coherence regardless of the current state of the human subject's heartbeat. Vaschillo analyzes, whereas the claimed invention instructs and achieves.

A further, but related distinction lies in the fact that Vaschillo performs its analysis in the frequency domain. The claimed invention is not analyzing data in the frequency domain and has no need to do so, because the claimed invention is not analyzing at what breathing frequency the uers's heartbeat is resonant. The claimed invention is instructing the human subject on how to breathe to reach coherence regardless of the current state of the human subject's heartbeat. This distinction is illustrated in the drawing below. This drawing represents Vaschillo's operation, wherein a phase difference is measured between the user's heartbeat and his breathing cycle to determine resonance, or lack thereof.



From the above, it is seen that Vaschillo has the user breathe at some "target" frequency during the assessment activity and at some later time. In the case of Vaschillo, this "target" frequency is achieved by having the user breathe at a rhythm at which the heart synchronizes with the breathing cycle. Breathing at the target frequency of the reference signal in Vaschillo is one means of achieving synchrony between breathing and heart rhythms, but it is not the method as claimed in claim 1, which uses the natural heart rate of the human subject.

Moreover, Vaschillo does not teach or suggest "wherein the instruction provided to the human subject to begin exhalation is provided by a first feedback type and the instruction provided to the human subject to begin inhalation is provided by a second feedback type." Vaschillo does not disclose two different feedback types to provide the instructions to the human subject to begin inhalation and exhalation. Thus, Vaschillo does not teach this element of claim 1. Accordingly, Vaschillo does not teach each and every element of claim 1 for this additional reason.

For the above reasons, Appellant respectfully submits that Vaschillo does not anticipate claim 1. Claims 5, 7, 9, 11-15, 17-20, 22, and 24 depend, either directly or indirectly, from claim 1. Accordingly, the rejection of claims 5, 7, 9, 11-15, 17-20, 22, and 24 should be withdrawn for at least the same reasons.

In addition, the Patent Office does not specifically address each of the dependent claims 5, 7, 9, 11-15, 17-20, 22, and 24 separately, but merely lumps the dependent claims in with claim 1. Thus, the Patent Office does not point to anything with particularity in Vaschillo that corresponds to the claimed limitation of dependent claims 5, 7, 9, 11-15, 17-20, 22, and 24. The

Patent Office has therefore failed to make a *prima facie* case of anticipation with respect to dependent claims 5, 7, 9, 11-15, 17-20, 22, and 24. Accordingly, dependent claims 5, 7, 9, 11-15, 17-20, 22, and 24 are patentable for this additional reason.

F. Claims 1, 5, 7, 9, 11-15, 17-20, And 22 Are Patentable Over Stabler

Claims 1, 5, 7, 9, 11-15, 17-20, and 22 stand rejected under 35 U.S.C. § 103(a) over Stabler. Appellant respectfully traverses the rejection. For the Patent Office to establish *prima facie* obviousness, the Patent Office must show where each and every claim element can be found in the reference. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. (BNA) 580 (CCPA 1974).

In contrast to the claimed invention, which achieving synchrony of the breathing cycle with the heart rhythm by monitoring the heart rate and consciously synchronizing the breathing cycle with the heart rhythm, Stabler, like Vaschillo, achieves synchrony of the heart rhythm with the breathing cycle by having the user breathe at a variable reference rhythm.

Like Vaschillo, Stabler has the user breathe with a reference rhythm in such a way as to achieve "the zone" (Stabler, Figure 1). Stabler defines the zone as a frequency range wherein the spectral power of the heart rate should be maximized. It can be assumed that Stabler's "zone" is indicative that the heart rhythm is nearing alignment with the breathing cycle. Stabler acknowledges that when performed correctly, the user's heart rate can be seen to "follow the breathing cycle" (Stabler, col. 3, paragraph 7).

Stabler does not instruct a human subject to have him breathe at a target rate based on the user's heart rate cycle (Stabler, col. 2, lines 35-38). Instead, Stabler simply displays a graph of heart rate variability and amplitude of breathing results to the user. The graph only indicates to the user that he is in "the zone," which Stabler makes clear is relative to the amplitude of the HRV cycle. Stabler does not teach or suggest that these results provide instructions to the user to breathe such that the user aligns his breathing cycle with his heart rate cycle. Nor does the user in Stabler breathe according to the results provided on the display. The user is simply given the results to indicate if the user is in the "zone" without any real understanding of the relationship of inhalations and exhalations to transitions in the natural heartbeat rate cycle (Stabler, col. 4, lines 1-17). Stabler simply requires the user to continue breathing in a controlled fashion until the user gets it right and reaches the "zone."

When the user is "in the zone," the heart rhythm will follow the breathing cycle. In Stabler, when the user is performing correctly, it should be seen that the heart rate is following the respiration (Stabler, col. 3, lines 53-64). Stabler's "zone" is also a broad indication of synchrony of the heart rhythm with the breathing cycle. Like Vaschillo, Stabler leads the heart rhythm to synchronize with the breathing cycle by having the user breathe at a rhythm at which the heart rhythm synchronizes with the breathing cycle.

However, this is fundamentally different than the claimed invention, which synchronizes the breathing cycle with the natural heart rate of the human subject by providing indications to inhale and exhale in synchrony with biofeedback signals derived from the human subject's natural heart rate. The key recognition of inhalation and exhalation in the breathing cycle to achieve coherence, as well as instructing the human subject specifically at the transition times as to when to inhale and exhale based on the human subject's natural heart rate, as set forth in the claimed invention, is not present in Stabler. Thus, Stabler does not render the claimed invention obvious, and thus this rejection must be withdrawn.

In addition, Stabler does not teach or suggest "wherein the instruction provided to the human subject to begin exhalation is provided by a first feedback type and the instruction provided to the human subject to begin inhalation is provided by a second feedback type." Stabler does not disclose two different feedback types to provide the instructions to the human subject to begin inhalation and exhalation. Thus, Stabler does not teach or suggest this element of claim 1. Accordingly, Stabler does not teach or suggest each and every element of claim 1 for this additional reason.

Claims 5, 7, 9, 11-15, 17-20, and 22 depend, either directly or indirectly, from claim 1. Accordingly, the rejection of claims 5, 7, 9, 11-15, 17-20, and 22 should be withdrawn for at least the same reasons as claim 1. In addition, the Patent Office does not specifically address each of the dependent claims 5, 7, 9, 11-15, 17-20, 22, and 24 separately, but merely lumps the dependent claims in with claim 1. Thus, the Patent Office does not point to anything with particularity in Stabler that corresponds to the claimed limitation of dependent claims 5, 7, 9, 11-15, 17-20, 22, and 24. The Patent Office has therefore failed to make a *prima facie* case of obviousness with respect to dependent claims 5, 7, 9, 11-15, 17-20, 22, and 24. Accordingly, dependent claims 5, 7, 9, 11-15, 17-20, 22, and 24 are patentable for this additional reason.

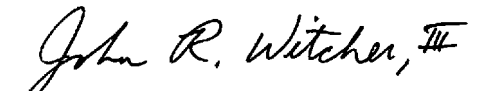
G. Conclusion

As set forth above, paragraphs 0007, 0010, 0019, 0021, 0022, and 0025-0037 of the Specification as published in U.S. Patent Application Publication No. 2005/0096555 A1, make clear to one of ordinary skill in the art that Appellant had possession of the claimed step of "instructing the human subject, via the second biofeedback signal, an exact moment to begin inhalation and instructing the human subject, via the first biofeedback signal, an exact moment to begin exhalation," as recited in claim 1. Therefore, the claims properly comply with the written description requirement under 35 U.S.C. § 112, first paragraph.

With respect to the anticipation and obviousness rejection of the claims, the Patent Office has not shown where all the elements of the pending claims are in the prior art with sufficient particularity to sustain an anticipation rejection or an obviousness rejection. In particular, the Patent Office has not shown where either Vaschillo or Stabler discloses or suggests each and every limitation of independent claim 1, for the reasons set forth above. In addition, the Patent Office has therefore failed to make a *prima facie* case of anticipation or obviousness with respect to dependent claims 5, 7, 9, 11-15, 17-20, 22, and 24 since the Patent Office does not point to anything with particularity in Vaschillo or Stabler that corresponds to the additional limitations of dependent claims 5, 7, 9, 11-15, 17-20, 22, and 24.

As such, for the above reasons, Appellant requests that the Board reverse the Examiner and instruct the Examiner to allow the claims.

Respectfully submitted,



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(8) CLAIMS APPENDIX

1. A method for consciously synchronizing a breathing cycle of a human subject with a natural heart rate of the human subject, the method comprising:

monitoring the natural heart rate of the human subject;

detecting a transition in the natural heart rate from a maximum heart rate;

providing a first biofeedback signal to the human subject to indicate that the natural heart rate has reached the maximum heart rate;

detecting a transition in the natural heart rate from a minimum heart rate;

providing a second biofeedback signal to the human subject to indicate that the natural heart rate has reached the minimum heart rate; and

instructing the human subject, via the second biofeedback signal, an exact moment to begin inhalation and instructing the human subject, via the first biofeedback signal, an exact moment to begin exhalation, such that the human subject aligns their breathing with the natural heart rate to attempt to achieve consistency in the natural heart rate, wherein the instruction provided to the human subject to begin exhalation is provided by a first feedback type and the instruction provided to the human subject to begin inhalation is provided by a second feedback type.

2-4. (Cancelled).

5. The method of claim 1 further comprising synchronizing the exact moment to begin inhalation with increasing heart rate associated with the detection of the transition in the natural heart rate from the minimum heart rate and synchronizing the exact moment to begin exhalation with decreasing heart rate associated with the detection of the transition in the natural heart rate from the maximum heart rate.

6. (Cancelled).

7. The method of claim 1 wherein instructing the exact moment to begin inhalation comprises providing the second feedback type on the basis of peak negative heart rate and

wherein instructing the exact moment to begin exhalation comprises providing the first feedback type on the basis of peak positive heart rate.

8. (Cancelled).

9. The method of claim 1 further comprising instructing the human subject on the exact moment to begin inhalation on the basis of peak negative heart rate plus one (1) heart beat and instructing the human subject on the exact moment to begin exhalation on the basis of peak positive heart rate minus one (1) heart beat.

10. (Cancelled).

11. The method of claim 1, wherein:

providing the first biofeedback signal includes providing the first biofeedback signal at the maximum heart rate minus a first programmable offset; and

providing the second biofeedback signal includes providing the second biofeedback signal at the minimum heart rate plus a second programmable offset.

12. The method of claim 11 wherein the first biofeedback signal informs the human subject to begin to exhale.

13. The method of claim 11 wherein the second biofeedback signal informs the human subject to begin to inhale.

14. The method of claim 11 wherein the first programmable offset is a percentage of the maximum heart rate of the human subject.

15. The method of claim 11 wherein the second programmable offset is a percentage of the minimum heart rate of the human subject.

16. (Cancelled).

17. The method of claim 11 wherein the first programmable offset is a number of heart beats after the maximum heart rate of the human subject.

18. The method of claim 11 wherein the second programmable offset is a number of heart beats after the minimum heart rate of the human subject.

19. The method of claim 11 further comprising presenting the human subject with a number of heart beats since the minimum heart rate and a number of heart beats since the maximum heart rate such that the human subject can consciously synchronize their own inhalation and exhalation on the basis thereof, respectively.

20. The method of claim 1 further comprising providing individual heart beats to the human subject in at least one of an audible, visual, and sensory format.

21. (Cancelled).

22. The method of claim 1 further comprising providing the first and second biofeedback signals on the basis of at least one of peak positive heart rate and peak negative heart rate.

23. (Cancelled).

24. The method of claim 1 further comprising instructing the human subject to synchronize a peak of an exhalation phase of a breathing cycle for the human subject with a peak negative heart rate and to synchronize a peak of an inhalation phase of the breathing cycle with a peak positive heart rate.

25. (Cancelled).

26. (Withdrawn) An instructive method for bringing the heart rate variability pattern of the typical untrained subject to an adequate state of coherence such that the present invention may be effectively employed:

a) the instructive method of applying electromyographic measurement techniques for the purpose of realizing adequate coherence of the heart rate variability signal,

b) the instructive method of next applying electroencephalo-graphic measurement techniques for the purpose or realizing adequate coherence of the heart rate variability signal.

27. (Withdrawn) The specific instructive method of claim 26, measuring the electrical potential at the location of the masseter muscle via electromyographic apparatus and instructing the subject to lower said potential while simultaneously monitoring for target coherence of the heart rate variability pattern with the present invention.

28. (Withdrawn) The specific instructive method of claim 26, next measuring the EEG potential in the high beta (26 Hertz) range and instructing the subject to lower said potential while simultaneously monitoring for target coherence of the heart rate variability pattern with the present invention.

29. (Withdrawn) The specific instructive method of claim 26, next measuring the EEG potential in the beta range (20 Hertz) and instructing the subject to lower said potential while simultaneously monitoring for target coherence of the heart rate variability pattern with the present invention.

30. (Withdrawn) A system for consciously synchronizing a breathing cycle of a human subject with a natural heart rate cycle of the human subject, the system comprising:

a pulse sensor adapted to produce a pulse output signal;

a pulse monitor adapted to monitor the natural heart rate of the human subject using the pulse output signal;

a positive and negative peak rate detector adapted to:

detect a transition in the monitored natural heart rate from a maximum heart rate; and

detect a transition in the monitored natural heart rate from a minimum heart rate; and

a criteria settings and comparator control system adapted to:

provide a first biofeedback signal to the human subject to indicate that the natural heart rate has reached the maximum heart rate; and

provide a second biofeedback signal to the human subject to indicate that the natural heart rate has reached the minimum heart rate.

31. (Withdrawn) The system of claim 30 wherein the criteria settings and comparator control system is further adapted to indicate, via the second biofeedback signal, an exact moment to begin inhalation and to indicate, via the first biofeedback signal, an exact moment to begin exhalation, and comprising a stimulus generator adapted to provide a first feedback type in response to the indication of the exact moment to begin exhalation and to provide a second feedback type in response to the indication of the exact moment to begin inhalation.

32. (Withdrawn) The system of claim 31 wherein the criteria settings and comparator control system is further adapted to synchronize the exact moment to begin inhalation with increasing heart rate associated with the detection of the transition in the monitored natural heart rate from the minimum heart rate and to synchronize the exact moment to begin exhalation with decreasing heart rate associated with the detection of the transition in the monitored natural heart rate from the maximum heart rate.

33. (Withdrawn) The system of claim 31 wherein the criteria settings and comparator control system is further adapted to indicate the exact moment to begin inhalation on the basis of peak negative heart rate and to indicate the exact moment to begin exhalation of the basis of peak positive heart rate.

34. (Withdrawn) The system of claim 31 wherein the criteria settings and comparator control system is further adapted to indicate the exact moment to begin inhalation on the basis of the peak negative heart rate plus one (1) heart beat and indicate the exact moment to begin exhalation on the basis of peak positive heart rate minus one (1) heart beat.

35. (Withdrawn) The system of claim 30, wherein the criteria settings and comparator control system is further adapted to:

provide the first biofeedback signal at the maximum heart rate minus a first programmable offset; and

provide the second biofeedback signal at the minimum heart rate plus a second programmable offset.

36. (Withdrawn) The method of claim 35, wherein the criteria settings and comparator control system is further adapted to instruct the human subject to begin to exhale in response to the first biofeedback signal.

37. (Withdrawn) The method of claim 35, wherein the criteria settings and comparator control system is further adapted to instruct the human subject to begin to inhale in response to the second biofeedback signal.

38. (Withdrawn) The system of claim 35 wherein the criteria settings and comparator control system is adapted to provide the first programmable offset as a percentage of the maximum heart rate of the human subject.

39. (Withdrawn) The system of claim 35 wherein the criteria settings and comparator control system is adapted to provide the second programmable offset as a percentage of the minimum heart rate of the human subject.

40. (Withdrawn) The system of claim 35 wherein the criteria settings and comparator control system is adapted to provide the first programmable offset as a number of heart beats after the maximum heart rate of the human subject.

41. (Withdrawn) The system of claim 35 wherein the criteria settings and comparator control system is adapted to provide the second programmable offset as a number of heart beats after the minimum heart rate of the human subject.

42. (Withdrawn) The system of claim 35 wherein the criteria settings and comparator control system is adapted to present the human subject with a number of heart beats since the minimum heart rate and a number of heart beats since the maximum heart rate such that the human subject can consciously synchronize their own inhalation and exhalation on the basis thereof, respectively.

43. (Withdrawn) The system of claim 30 comprising a stimulus generator adapted to provide at least one of audible, visual, and sensory outputs, and wherein the criteria settings and comparator control system is further adapted to receive indications of individual heartbeats from the pulse monitor and to provide the indications of the individual heart beats to the human subject via at least one of the audible, visual, and sensory outputs of the stimulus generator.

44. (Withdrawn) The system of claim 30 wherein the criteria settings and comparator control system is further adapted to provide the first and second biofeedback signals on the basis of at least one of peak positive heart rate and peak negative heart rate.

45. (Withdrawn) The system of claim 30 wherein the criteria settings and comparator control system is further adapted to instruct the human subject to synchronize a peak of an exhalation phase of the breathing cycle for the human subject with the peak negative heart rate and to synchronize a peak of an inhalation phase of the breathing cycle with the peak positive heart rate.

(9) EVIDENCE APPENDIX

Appellant relies on no evidence, thus this appendix is not applicable.

(10) RELATED PROCEEDINGS APPENDIX

As there are no related proceedings, this appendix is not applicable.